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EXAMINER	
BAUM, STUART F	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 09/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,364	BOUTILER ET AL.	
	Examiner	Art Unit	
	Stuart F. Baum	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-74* is/are pending in the application.

4a) Of the above claim(s) *5,18,28-36,54-58 and 61-74* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,7,10-17,19-27,37-53,59 and 60* is/are rejected.

7)☒ Claim(s) *8-9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *sequence search results*.

DETAILED ACTION

1. The amendment filed 6/24/2004 has been entered.

Claims 1-74 are pending.

2. Applicant's election with traverse of Group I, claims 1-17, 19-27, 37-53 and 59-60, including SEQ ID NO:1 encoding SEQ ID NO:2 in the reply filed on 6/24/2004 is acknowledged.

The traversal is on the ground(s) that the BMN3A and BMN3B proteins of SEQ ID NO:2 and 4, respectively, are extremely closely related in sequence. Applicants contend that the proteins differ only in 13 amino acids out of a total of 579 amino acids. Applicants also contend that the encoding cDNA fragments are very closely related as supported by Figure 2 (page 13, 2nd paragraph).

3. SEQ ID NO:3 encoding SEQ ID NO:4 has been rejoined.

The requirement is still deemed proper and is therefore made FINAL.

Claims 5, 18, 28-36, 54-58, and 61-74 have been withdrawn from consideration for being drawn to non-elected inventions.

4. Claims 1-4, 6-17, 19-27, 37-53, and 59-60 including SEQ ID NO:1 encoding SEQ ID NO:2, and SEQ ID NO:3 encoding SEQ ID NO:4 are examined in the present office action.

Specification

5. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or

other form of browser-executable code. See for example page 23, 4th paragraph. See MPEP § 608.01.

Claim Objections

6. Claims 1-4 and 6-7 are objected to for reading on non-elected inventions. Correction is requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 19-24, 37, 44-45, and 51-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection includes dependent claims.

Claim 19 recites the limitation "said transformed plant" in line 6. There is insufficient antecedent basis for this limitation in the claim.

Claim 37 provides for the use of a nucleotide sequence as defined in claim 4, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 44 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The preamble of the claim recites "a method of modifying the

regenerative capacity of a plant" but the last step of the claim recites "assaying said tissue for enhanced regeneration...". Applicant does not include a step for regenerating a plant from the transformed tissue.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 37 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-4, 6-7, 10-17, 19-27, 37-53, and 59-60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated DNA molecule comprising a nucleotide sequence that hybridizes to SEQ ID NO:1 or 3 under moderate or stringent conditions, or a fragment or derivative thereof, excluding an AP2 domain repeat1-linker-AP2 domain repeat2 region, under moderate or stringent hybridization conditions, or wherein said nucleotide sequence comprises at least 27 contiguous nucleotides of SEQ ID NO:1 or 3, or wherein said isolated DNA molecule is at least 70% homologous with a nucleotide sequence, or fragment or derivative thereof, taken from SEQ ID NO:1or 3, or an isolated DNA molecule comprising a nucleic acid sequence that encodes a protein wherein the protein performs a function as recited in claim 4 and wherein said isolated DNA molecule has at least 70% homology within a nucleotide sequence, or a fragment or derivative thereof, from SEQ ID NO:1 or 3, or wherein said isolated DNA molecule encodes a protein that is at least 70% similar with the amino acid sequence defined by SEQ ID NO:2 or 4, a vector comprising said DNA molecule operably linked to a regulatory element operable in plant cells, or a plant cell or plant transformed with said vector, and seed thereof, or methods of producing asexually derived embryos, modifying regenerative capacity, producing an apomictic plant or selecting a modified plant comprising said vector. Absent evidence to the contrary, the Office interprets "homology" or "homologous" to mean sequence "identical" or "sequence identity".

Applicants' invention was isolated using a subtractive screening approach to isolate genes preferentially expressed during the induction of *Brassica napus* c.v. Topas microspore embryogenesis (page 52, 1st sentence of Example 1). Two cDNA clones, BNM3A of SEQ ID NO:1 and BNM3B of SEQ ID NO:3 were isolated from a 10 day old microspore embryo cDNA library. The two BNM3 cDNA clones are 2011 and 1992 nt in length and are 97% similar at the

nucleotide level, differing only slightly in the length and sequence of their 5' and 3' untranslated regions. Applicants disclose that both cDNAs potentially encode 579 amino acid polypeptides that are 97% similar at the amino acid level (page 53, 1st paragraph of Example 2-1). Applicants also disclose the isolation of the Arabidopsis genomic BNM3 orthologue (page 55, last paragraph and paragraph bridging page 56 and 57).

There are two main issues that are presented in the written description rejection.

Issue #1) Applicants report that polypeptides encoded by SEQ ID NO:1 and 3 are 97% similar at the amino acid level (page 53, last sentence of 1st paragraph). But, the two respective polypeptides that are disclosed in Applicants' sequence listing are 100% identical to each other. It appears that Applicants have deposited the same polypeptide sequence for both SEQ ID NO:2 and SEQ ID NO:4 which is contrary to Applicants' disclosure.

Issue #2) The Applicants do not identify essential regions of the protein encoded by SEQ ID NO:1 or 3, nor do Applicants describe any polynucleotide sequences that hybridize to a fragment of SEQ ID NO:1 or 3 that encodes a protein with the same function as the protein encoded by SEQ ID NO:1 or 3. The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative

number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Applicants fail to describe a representative number of polynucleotide sequences encoding a protein falling within the scope of the claimed genus of polynucleotides which hybridize to a fragment of SEQ ID NO:1 or 3. Applicants only describe the two BNM3 cDNA clones and a single genomic orthologue from Arabidopsis (page 55, last paragraph). Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides that are specific to the genus of BNM3 polypeptides that is outside the AP2 domain. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the protein encoded by SEQ ID NO:1 or 3, it remains unclear what features identify a *Brassica* BNM3 polypeptide encoded by SEQ ID NO:1 or 3. Since the genus of said polypeptides has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Scope of Enablement

9. Claims 1-4, 6-7, 10-17, 19-27, 37-53, and 59-60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for and isolated DNA molecule comprising SEQ ID NO:1 encoding SEQ ID NO:2 or SEQ ID NO:3 encoding SEQ ID NO:4, or a vector comprising said isolated DNA molecule operably linked to a promoter and plant transformation therewith, and method of producing asexually derived embryos and method for

increasing the regenerative capacity of a plant comprising transforming a plant with said vector, does not reasonably provide enablement for any isolated DNA molecule that exhibits less than 100% sequence identity to SEQ ID NO:1 or 3, a vector comprising said DNA molecule operably linked to any promoter and plant transformation therewith, and method of producing gametophytic embryos, haploid parthenogenesis of the embryo sac or diplospory or method of selecting a transformed plant comprising transforming a plant with said DNA molecule; method of producing asexually derived embryos or method of modifying the regenerative capacity of a plant, comprising transient transformation of a plant cell with said isolated DNA molecule; or method of producing an apomictic plant comprising transforming a plant with said DNA molecule and transformed plants are assayed for gametophytic embryos or parthenogenesis of the embryo sac. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to an isolated DNA molecule comprising a nucleotide sequence that hybridizes to SEQ ID NO:1 or 3 under moderate or stringent conditions, or a fragment or derivative thereof, excluding an AP2 domain repeat1-linker-AP2 domain repeat2 region, under moderate or stringent hybridization conditions, or wherein said nucleotide sequence comprises at least 27 contiguous nucleotides of SEQ ID NO:1 or 3, or wherein said isolated DNA molecule is at least 70% homologous with a nucleotide sequence, or fragment or derivative thereof, taken from SEQ ID NO:1or 3, or an isolated DNA molecule comprising a nucleic acid sequence that encodes a protein wherein the protein performs a function as recited in claim 4 and wherein said isolated DNA molecule has at least 70% homology within a nucleotide sequence, or a fragment or derivative thereof, from SEQ ID NO:1 or 3, or wherein said isolated DNA molecule encodes a protein that is at least 70% similar with the amino acid sequence defined by SEQ ID NO:2 or 4, a vector comprising said DNA molecule operably linked to a regulatory element operable in plant cells, or a plant cell or plant transformed with said vector, and seed thereof, or methods of producing asexually derived embryos, modifying regenerative capacity, producing an apomictic plant or selecting a modified plant comprising transforming a plant or plant cell or transiently transforming a plant or plant cell with said vector. Absent evidence to the contrary, the Office interprets "homology" or "homologous" to mean sequence "identical" or "sequence identity".

Applicants' invention was isolated using a subtractive screening approach to isolate genes preferentially expressed during the induction of *Brassica napus* c.v. Topas microspore embryogenesis (page 52, 1st sentence of Example 1). Two cDNA clones, BNM3A of SEQ ID NO:1 and BNM3B of SEQ ID NO:3 were isolated from a 10 day old microspore embryo cDNA library. The two BNM3 cDNA clones are 2011 and 1992 nt in length and are 97% similar at the

nucleotide level, differing only slightly in the length and sequence of their 5' and 3' untranslated regions. Applicants disclose that both cDNAs potentially encode 579 amino acid polypeptides that are 97% similar at the amino acid level (page 53, 1st paragraph of Example 2-1). Applicants also disclose the isolation of the Arabidopsis genomic BNM3 orthologue (page 55, last paragraph and paragraph bridging page 56 and 57). Applicants also disclose overexpressing the BNM3 cDNAs in Arabidopsis comprising transforming Arabidopsis with the BNM3 cDNAs operably linked to constitutive promoter promotes the formation of somatic embryos on vegetative structures such as cotyledons, petioles, leaf blades and shoot apical meristems (page 58, top paragraph). Overexpression of BNM3 cDNAs in Arabidopsis also caused root explants to exhibit an increase in shoot regeneration even when the explants were regenerated in the absence of added growth regulators, when compared to non-transformed plants (page 59, 1st and second paragraphs).

The state-of-the-art is such that one of skill in the art cannot predict which nucleic acids that hybridize to SEQ ID NO:1 or 3, or hybridize to a fragment of SEQ ID NO:1 or 3 under moderate or stringent hybridization conditions will encode a protein with the same activity as a protein encoded by SEQ ID NO:1 or 3. Even DNA molecules encoding a protein that is 70% similar to the amino acid sequence of SEQ ID NO:2 or 4 will not necessarily encode a polypeptide with the same activity as the polypeptide of SEQ ID NO:2 or 4. The prediction of protein structure from sequence data and, in turn, utilizing predicted structural determinations to ascertain functional aspects of the protein, is extremely complex, and the positions within the protein's sequence where amino acid substitutions can be made with a reasonable expectation of maintaining function are limited (Bowie et al, Science 247:1306-1310, 1990, see especially page

1306). Proteins may be sensitive to alterations in even a single amino acid in a sequence. For example, the replacement of a glycine residue located within the START domain of either the PHABULOSA or PHAVOLUTA protein receptor with either an alanine or aspartic acid residue, alters the sterol/lipid binding domain (McConnell et al, Nature 411 (6838):709-713, 2001, see especially page 710, left column, 2nd paragraph).

Applicants claims are drawn to nucleic acid sequences that hybridize to SEQ ID NO:1 or 3, but the state-of-the-art teaches isolating DNA fragments using stringent hybridization conditions, does not always select for DNA fragments whose contiguous nucleotide sequence is the same or nearly the same as the probe. Fourgoux-Nicol et al (1999, Plant Molecular Biology 40 :857-872) teach the isolation of a 674bp fragment using a 497bp probe incorporating stringent hybridization conditions comprising three consecutive 30 minute rinses in 2X, 1X and 0.1X SSC with 0.1% SDS at 65^0C (page 859, left column, 2nd paragraph). Fourgoux-Nicol et al also teach that the probe and isolated DNA fragment exhibited a number of sequence differences comprising a 99bp insertion and a single nucleotide gap, while the DNA fragment contained 2 single nucleotide gaps and together the fragments contained 27 nucleotide mismatches. Taking into account the insertions, gaps and mismatches, the longest stretch of contiguous nucleotides to which the probe could hybridize consisted of 93bp of DNA (page 862, Figure 2).

Applicants' claims are broadly drawn and encompass nucleic acid molecules that do not encode proteins with the same function as the protein encoded by SEQ ID NO:1 or 3. In fact, Applicants' claims read on a promoter sequence. Turner et al (November, 2000, WO 00/70058) teach a nucleic acid sequence of SEQ ID NO:3 that is a cellulose synthase promoter and does not encode a polypeptide that when transformed into a plant or plant cell increases the regenerative

capacity of said plant or renders said plant cell embryogenic. Said promoter would hybridize with SEQ ID NO:1 or 3 under moderate or stringent hybridization conditions (page 20, 3rd paragraph and pages 32-33, claims 8-13).

A portion of Applicants' method claims are drawn to transiently transforming a plant cell with the vector of claim 10, but Applicants have only disclosed examples in which plants or plant cells are stably transformed with a nucleic acid molecule. The Office interprets "transiently transforming" as a process in which nucleic acid molecules are introduced into plant cells but the nucleic acid molecules are not integrated into the plant cell's genome. Given that the nucleic acid molecules are not integrated into the plant cell's genome, the introduced DNA would not be transferred to progeny cells and as such would not affect the development of said cells. Given any evidence to the contrary, plant cells transiently transformed with nucleic acid molecules would not produce the desired result and as such, are not enabled.

Applicants have not disclosed how one makes or isolates any of the sequences that are encompassed by Applicants' broad claims. Applicants have not taught which regions of the respective polynucleotides can be used to amplify any of said polynucleotides or which regions can be used as a probe to isolate any of said polynucleotide sequences.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of SEQ ID NO:1 or 3 as probes or by designing primers to undisclosed regions of SEQ ID NO:2 and 4 and isolating or amplifying fragments, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to

identify those, if any, that when over-expressed produce asexual derived embryos or increase the regenerative capacity of a plant and exhibit 70% homology to a fragment of SEQ ID NO:1 or 3.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claim 17 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 17 is drawn to a seed of the transformed plant. Due to Mendelian inheritance of genes, a single gene introduced into a parent plant would only be transferred at most to half the male gametes and half the female gametes. This translates into only three quarters of the progeny having at least a single copy of the transgene and one quarter of the progeny would not carry a copy of the transgene. Given that there is no indication that there would be any other distinguishable characteristics of the claimed progeny (seeds), it is unclear whether the claimed seeds would be distinguishable from seeds that would occur in nature. See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948), and *In re Bergy , Coats, and Malik* 195 USPQ 344, (CCPA) 1977. The amendment of the claims to recite that the seeds comprise the construct that was introduced into the parent seed would overcome the rejection.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Elliott et al (1996, The Plant Cell 8(2):155-168).

The claims are drawn to an isolated DNA molecule that hybridizes to a fragment of SEQ ID NO:1 or 3 wherein said isolated DNA molecule comprises a nucleotide sequence that is at least 70% homologous with a fragment of SEQ ID NO:1 or 3, excluding an AP2 domain repeat1-linker-AP2 domain repeat2 region. Applicants define said region by nucleotides 741-1257 of SEQ ID NO:1 (page 23, paragraph i). The Office interprets "homologous" to mean "sequence identical".

Elliott et al disclose a nucleic acid molecule that encodes an AINTEGUMENTA protein, said nucleic acid molecule comprises a fragment that exhibits at least 70% sequence identity to a fragment of SEQ ID NO:1 and would hybridize under moderate or stringent hybridization conditions to Applicants invention. Said fragment defined as nucleotides 851-877 of the sequence disclosed by Elliott et al which is greater than 70% sequence identity to nucleotides 714-740 of Applicants' SEQ ID NO:1 (See sequence search results), and as such, Elliott et al anticipate the claimed invention.

12. Claims 2, 4, 6-17, 19-27, 37-53, and 59-60 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated DNA molecule of SEQ ID NO:1 or 3 encoding SEQ ID NO:2 or 4, respectively, a vector comprising said molecule operably linked to a promoter and plant or plant cell transformed therewith, and method of producing asexually derived embryos, method of modifying the regenerative capacity of a plant, a method of selecting a transformed plant and method of producing an apomictic plant comprising transforming a plant cell with said vector.

13. Claims 8 and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. Claims 1-4, 6-7, 10-17, 19-27, 37-53, and 59-60 are not allowable.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.
Patent Examiner
Art Unit 1638
September 13, 2004

AMY J. NELSON, PH.D
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